WEC

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN



UNITED STATES OF AMERICA,

Plaintiff,

v. Case No. 10-CR-253

VITAL HEALTH PRODUCTS, LTD.,

Defendant.

## PLEA AGREEMENT

1. The United States of America, by its attorneys, James L. Santelle, United States Attorney for the Eastern District of Wisconsin, and Gordon P. Giampietro, Assistant United States Attorney, and the defendant, Vital Health Products, Ltd., by its duly authorized representative, Conrad E. LeBeau, and its attorney Joanna T. Perini, Associate Federal Defender, pursuant to Rule 11 of the Federal Rules of Criminal Procedure, enter into the following plea agreement:

### CHARGES

2. The defendant has been charged in a four-count information that alleges violations of Title 21, United States Code, Sections 331(d), 355, and 333(a)(1).

3. The defendant, by its duly authorized representative, has read and fully understands the charges contained in the information and fully understands the nature and elements of the crimes with which it has been charged. In addition, those charges and the

terms and conditions of the plea agreement have been fully explained to the defendant's representative by its attorney.

4. The defendant, by its duly authorized representative, voluntarily agrees to plead guilty to the offense charged as count three of the Information, which is set forth in pertinent part as follows:

***THE UNITED STATES ATTORNEY FURTHER CHARGES:***

*12. On or about the dates listed below, in the State and Eastern District of Wisconsin,*

***VITAL HEALTH PRODUCTS, LTD., and***
***CONRAD E. LEBEAU***

*introduced and caused the introduction into interstate commerce of the drugs listed below, which were new drugs within the meaning of 21 U.S.C. § 321(p)(1), and which were not approved for their intended use in the United States, as they did not have in effect with the FDA an approved New Drug Application, Abbreviated New Drug Application, or Investigational New Drug Application:*

| ***COUNT*** | ***DATE*** | ***PRODUCT NAME*** | ***DISEASE CLAIM*** |
|---|---|---|---|
| *1* | | | |
| *2* | | | |
| *3* | *10/7/09* | *Perfect Colon Formula #1* | *"Reduces Food allergies"* |
| *4* | | | |

*All in violation of 21 U.S.C. §§ 331(d), 355, and 333(a)(1).*

5. The defendant, by its duly authorized representative, acknowledges, understands, and agrees that it is, in fact, guilty of the offense charged in count three. The parties acknowledge and understand that if this case were to proceed to trial, the government would be able to prove the following facts beyond a reasonable doubt. The defendant admits to these facts and that these facts establish its guilt beyond a reasonable doubt:

The Federal Food, Drug, and Cosmetic Act

One of the purposes of The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399a, is to ensure that drugs sold for administration to humans are approved by the FDA as both safe and effective for their intended uses. Under the FDCA, a drug is defined to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals or intended to affect the structure or any function of the human body." *See* 21 U.S.C. § 321(g). A "new drug" is any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. . . ." *See* 21 U.S.C. § 321(p)(1).

Further, the FDCA specifies that no new drug may be introduced or delivered for introduction into interstate commerce unless the FDA has approved a new drug application or an abbreviated new drug application with respect to the drug, or unless the FDA has otherwise exempted the drug as an investigational new drug. *See* 21 U.S.C. § 355. The

introduction or delivery for introduction into interstate commerce of an unapproved new drug is prohibited. *See* 21 U.S.C. § 331(d). These FDCA requirements were in effect at all times relevant to the Information.

Background of Defendant's Business

Since at least 1987, the defendant Conrad E. LeBeau ("LeBeau") has been engaged in the business of manufacturing and selling products that he claims mitigate, treat, and prevent various diseases. LeBeau conducted his business under the name Vital Health Products, Ltd. ("Vital Health"), an entity that, at all times relevant to the Information, was an active Wisconsin limited liability company with an office in West Allis, Wisconsin. At all times relevant to the Information, LeBeau exercised sole authority and control over Vital Health's business, including maintaining a website, www.myvitalhealth.info, and processing and shipping products ordered from that website. LeBeau offered for sale, sold, and shipped products formulated by third-parties, and those that he himself formulated.[1]

Since 1992, LeBeau and Vital Health operated under a permanent injunction issued in Case No. 91-C-363, Eastern District Court of Wisconsin, that was subsequently affirmed by the Seventh Circuit Court of Appeals in *United States v. Lebeau*, 985 F.2d 563, 1993 WL 21970 (7th Cir. 1993).

[1] In this plea agreement, references to LeBeau or Vital Health are interchangeable because LeBeau controlled Vital Health and was responsible for all aspects of its business.

Under the terms of the injunction, LeBeau and Vital Health were permanently enjoined from "promoting, labeling, advertising, or representing that . . . any other product constituting a drug under the 21 U.S.C. § 321(g), is safe and effective in the cure, mitigation, treatment, or prevention of human disease, unless and until an approved new drug application authorizing such representations is in effect for such product, as required by 21 U.S.C. § 355(a)." 1993 WL 21970, p. 19.

Offense Conduct

In the Spring and Fall of 2009, agents with the FDA's Office of Criminal Investigations reviewed the products that LeBeau and Vital Health offered for sale on their website, www.myvitalhealth.info, and purchased a number of products for interstate shipment to the FDA-OCI's P.O. Box in Downers Grove, Illinois. Selected for purchase were products for which the defendants made "disease claims" in violation of the FDCA. In particular, and as it relates to count three of the Information, the defendants claimed on their website that use of the product, Perfect Colon Formula #1, "reduces food allergies." On or about October 7, 2009, the defendants caused the shipment of one bottle of Perfect Colon Formula #1 from West Allis, Wisconsin, to Downers Grove, Illinois.

If this case were to proceed to trial, FDA experts would testify that Perfect Colon Formula #1 is a new drug under 21 U.S.C. § 321(p)(1) because its "composition" is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the

conditions prescribed, recommended, or suggested in the labeling thereof. . . ." Stated more plainly, Perfect Colon Formula # 1 has not been generally recognized by qualified experts as safe and effective in helping to "reduce[] food allergies."

FDA experts would further testify that, on or about October 7, 2009, the date on which the defendants shipped Perfect Colon Formula #1 in interstate commerce, the FDA had not approved a new drug application, or an abbreviated new drug application, with respect to Perfect Colon # 1, or otherwise exempted it as an investigational new drug, as required by 21 U.S.C. § 355.

This information is provided for the purpose of setting forth a factual basis for the plea of guilty. It is not a full recitation of the defendant's knowledge of, or participation in, this offense.

**PENALTIES**

6. The parties understand and agree that the offense to which the defendant will enter a guilty plea, Title 21, United States Code, Section 331(d), carries a maximum fine of $200,000 under Title 18, United States Code, Section 3571(c)(5); a maximum term of probation of 5 years under Title 18, United States Code, Section 3561(c)(2) and Sentencing Guidelines Manual § 8D1.2(a)(2); and a mandatory special assessment of $125 pursuant to Title 18, United States Code, Section 3013(a)(1)(B)(iii).

## ELEMENTS

7. The parties understand and agree that in order to sustain the charge of *introducing unapproved new drugs into interstate commerce* as set forth in count three, the government must prove each of the following propositions beyond a reasonable doubt:

First, the product is a "drug" within the meaning of 21 U.S.C. § 321(g)(1);

Second, the drug is a "new drug" within the meaning of 21 U.S.C. § 321(p)(1);

Third, the FDA has neither approved nor exempted it from approval pursuant to 21 U.S.C. § 355; and

Fourth, that the defendant caused the unapproved new drug to be introduced or delivered for introduction into interstate commerce.[2]

## SENTENCING PROVISIONS

8. The parties agree to waive the time limits in Fed. R. Crim. P. 32 relating to the presentence report, including that the presentence report be disclosed not less than 35 days before the sentencing hearing, in favor of a schedule for disclosure, and the filing of any objections, to be established by the court at the change of plea hearing.

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[2] There is no state of mind requirement for misdemeanor offenses under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399a. The FDCA was designed as a strict liability statute to protect society at large. The "government need not prove knowledge or awareness that the drugs are misbranded or an intent to deceive or defraud." *United States v. Articles of Drug*, 825 F.2d 1238, 1246 (8th Cir.1987); *see also Rheinecker v. Forest Laboratories, Inc.*, 813 F.Supp. 1307, 1311 (S.D.Ohio 1993) (explaining violations of the FDCA, 21 U.S.C. § 301 et seq., "attach [ ] without any proof of intent, knowledge or awareness of wrongdoing")(citing *United States v. Park*, 421 U.S. 658, 672-73 (1975)); *see also United States v. Dotterweich*, 320 U.S. 277, 280-81 (1943).

9. The parties acknowledge, understand, and agree that any sentence imposed by the court will be pursuant to the Sentencing Reform Act, and that the court will give due regard to the Sentencing Guidelines when sentencing the defendant.

10. The parties acknowledge and agree that they have discussed all of the sentencing guidelines provisions which they believe to be applicable to the offense set forth in paragraph 4.

**Sentencing Guidelines Calculations**

11. The parties acknowledge, understand, and agree that the sentencing guidelines calculations included in this agreement represent the positions of the parties on the appropriate sentence range under the sentencing guidelines. The defendant acknowledges and understands that the sentencing guidelines recommendations contained in this agreement do not create any right to be sentenced within any particular sentence range, and that the court may impose a reasonable sentence above or below the guideline range. The parties further understand and agree that if the defendant has provided false, incomplete, or inaccurate information that affects the calculations, the government is not bound to make the recommendations contained in this agreement.

**Relevant Conduct**

12. The parties acknowledge, understand, and agree that pursuant to Sentencing Guidelines Manual § 1B1.3, the sentencing judge may consider relevant conduct in

calculating the sentencing guidelines range, even if the relevant conduct is not the subject of the offense to which defendant is pleading guilty.

**Base Offense Level**

13. The parties agree to recommend to the sentencing court that the applicable base offense level for the offense charged in count three is 6 under Sentencing Guidelines Manual § 2N2.1(a).

14. The parties further agree to recommend to the sentencing court that a fine be imposed pursuant to Sentencing Guidelines Manual § 8C2.10 and Title 18, United States Code, Sections 3553 and 3572

**Sentencing Recommendations**

15. Both parties reserve the right to apprise the district court and the probation office of any and all information which might be pertinent to the sentencing process, including but not limited to any and all conduct related to the offense as well as any and all matters which might constitute aggravating or mitigating sentencing factors.

16. Both parties reserve the right to make any recommendation regarding any other matters not specifically addressed by this agreement.

17. The government and the defendant agree to recommend that a $400 fine be imposed as the sentence in this case.

## Court's Determinations at Sentencing

18. The parties acknowledge, understand, and agree that neither the sentencing court nor the United States Probation Office is a party to or bound by this agreement. The United States Probation Office will make its own recommendations to the sentencing court. The sentencing court will make its own determinations regarding any and all issues relating to the imposition of sentence and may impose any sentence authorized by law up to the maximum penalties set forth in paragraph 6 above. The parties further understand that the sentencing court will be guided by the sentencing guidelines but will not be bound by the sentencing guidelines and may impose a reasonable sentence above or below the calculated guideline range.

19. The parties acknowledge, understand, and agree that the defendant may not move to withdraw the guilty plea solely as a result of the sentence imposed by the court.

## FINANCIAL MATTERS

### Fine

20. As set forth in paragraph 17, the parties agree to recommend to the sentencing court that, under Sentencing Guidelines Manual § 8C2.10, the defendant pay a fine in the amount of $400.00.

### Special Assessment

21. The defendant agrees to pay the special assessment in the amount of $125.00 prior to or at the time of sentencing.

## Restitution

22. The parties agree that there is no restitution due and owing as a result of the offense of conviction.

## DEFENDANT'S WAIVER OF RIGHTS

23. In entering this agreement, the defendant acknowledges and understands that in so doing it surrenders any claims it may have raised in any pretrial motion as well as certain rights which include the following:

a. If the defendant persisted in a plea of not guilty to the charges against it, it would be entitled to a speedy and public trial by a court or jury. The defendant has a right to a jury trial. However, in order that the trial be conducted by the judge sitting without a jury, the defendant, the government and the judge all must agree that the trial be conducted by the judge without a jury.

b. If the trial is a jury trial, the jury would be composed of twelve citizens selected at random. The defendant would have a say in who the jurors would be by removing prospective jurors for cause where actual bias or other disqualification is shown, or without cause by exercising peremptory challenges. The jury would have to agree unanimously before it could return a verdict of guilty. The court would instruct the jury that the defendant is presumed innocent until such time, if ever, as the government establishes guilt by competent evidence to the satisfaction of the jury beyond a reasonable doubt.

c. If the trial is held by the judge without a jury, the judge would find the facts and determine, after hearing all of the evidence, whether or not he was persuaded of defendant's guilt beyond a reasonable doubt.

d. At such trial, whether by a judge or a jury, the government would be required to present witnesses and other evidence against the defendant. The defendant would be able to confront witnesses upon whose testimony the government is relying to obtain a conviction and he would have the right to cross-examine those witnesses. In turn the

defendant could, but is not obligated to, present witnesses and other evidence on its own behalf. The defendant would be entitled to compulsory process to call witnesses.

24. The defendant acknowledges and understands that by pleading guilty it is waiving all the rights set forth above. The defendant further acknowledges that as a part of the guilty plea hearing, the court may question the defendant's representative under oath and on the record, about the offense to which the defendant intends to plead guilty. The defendant's representative further understands that his answers may later be used against him in a prosecution for perjury or false statement.

25. The defendant knowingly and voluntarily waives all claims it may have based upon the statute of limitations, the Speedy Trial Act, and the speedy trial provisions of the Sixth Amendment. The defendant agrees that any delay between the filing of this agreement and the entry of the defendant's guilty plea pursuant to this agreement constitutes excludable time under the Speedy Trial Act.

**Further Civil or Administrative Action**

26. The defendant acknowledges, understands, and agrees that this plea agreement does not preclude further civil or administrative action by the government related to its distribution of FDA-regulated products, now or at any time in the future.

27. As an express condition of this plea agreement, the defendant agrees it will immediately cease and refrain in the future from:

a. causing to be introduced or delivered for introduction into interstate commerce;

b. holding for sale after shipment in interstate commerce; and

c. manufacturing, packing, processing, and distributing,

any drug as defined by 21 U.S.C. § 321(g)(1) unless and until FDA has approved a new drug application or abbreviated new drug application filed by the defendant pursuant to 21 U.S.C. § 355(b) or (j) or the defendant has obtained from FDA an investigational new drug application ("IND") filed pursuant to 21 U.S.C. § 355(i) and the defendant's distribution of such drug takes place solely for the purpose of conducting clinical investigations in strict accordance with the protocol as authorized as part of the IND application.

**Marketing Pre-notification Requirement**

28. Ten days prior to distributing any food, dietary supplement, or drug in interstate commerce, the defendant shall notify the Milwaukee FDA in writing of the name of the product or products and provide information on the labeling thereof.

**GENERAL MATTERS**

29. The parties acknowledge, understand, and agree that this agreement does not require the government to take, or not to take, any particular position in any post-conviction motion or appeal.

30. The parties acknowledge, understand, and agree that this plea agreement will be filed and become part of the public record in this case.

31. The parties acknowledge, understand, and agree that the United States Attorney's office is free to notify any local, state, or federal agency of the defendant's conviction.

32. The defendant understands that pursuant to the Victim and Witness Protection Act and the regulations promulgated under the Act by the Attorney General of the United States, the victim of a crime may make a statement describing the impact of the offense on the victim and further may make a recommendation regarding the sentence to be imposed. The defendant acknowledges and understands that comments and recommendations by a victim may be different from those of the parties to this agreement.

**EFFECT OF DEFENDANT'S BREACH OF PLEA AGREEMENT**

33. The defendant acknowledges and understands if he violates any term of this agreement at any time, engages in any further criminal activity prior to sentencing, or fails to appear for sentencing, this agreement shall become null and void at the discretion of the government. The defendant further acknowledges and understands that the government's agreement to dismiss any charge is conditional upon final resolution of this matter. If this plea agreement is revoked, or if the defendant's conviction hereunder ultimately is overturned, then the government retains the right to reinstate any and all dismissed charges and to file any and all charges which were not filed because of this agreement. The defendant hereby knowingly and voluntarily waives any defense based on the applicable statute of limitations for any charges filed against the defendant as a result of its breach of

this agreement. The defendant understands, however, that the government may elect to proceed with the guilty plea and sentencing.

## VOLUNTARINESS OF DEFENDANT'S PLEA

34. The defendant, but its duly authorized representative, acknowledges, understands, and agrees that it will plead guilty freely and voluntarily. The defendant further acknowledges and agrees that no threats, promises, representations, or other inducements have been made, nor agreements reached, other than those set forth in this agreement, to induce the defendant to plead guilty.

## ACKNOWLEDGMENTS

I am a duly authorized representative of the defendant. I am entering into this plea agreement on behalf of the defendant freely and voluntarily. The attorney for the defendant has reviewed every part of this agreement with me and have advised me, on behalf of the defendant, of the implications of the sentencing guidelines. I have discussed all aspects of this case with Attorney Joanna T. Perini, and I am satisfied that she has provided effective assistance of counsel.

Date: Jan 13 2012

Conrad E LeBeau

VITAL HEALTH PRODUCTS, LTD.
By its duly authorized representative
CONRAD E. LEBEAU

I am the defendant's attorney. I carefully have reviewed every part of this agreement with the defendant's representative, Conrad E. LeBeau. To my knowledge, my client's decision to enter into this agreement is an informed and voluntary one.

Date: 1/12/12

Joanna T. Perini

JOANNA T. PERINI
ASSOCIATE FEDERAL DEFENDER
Attorney for Defendant

For the United States of America:

Date: 1/12/12

JAMES E. SANTELLE
United States Attorney

Date: 1/12/12

GORDON P. GIAMPIETRO
Assistant United States Attorney